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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,596	02/09/2001	Jean-Richard Nceser	88265-406	6562

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/779,596	NEESER ET AL.
	Examiner	Art Unit
	Kathleen M Kerr	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,4,6,7,9,10 and 23-29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 29 is/are allowed.
- 6) Claim(s) 1,2,4,6,7,9,10 and 23-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, an Advisory action (mailed on January 29, 2004), Applicants filed an RCE and amendment received on March 4, 2004. Said amendment cancelled Claims 8 and amended Claims 1 and 7. Thus, Claims 1, 3, 4, 6, 7, 9, 10, and 23-29 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application requests the benefit of priority for the foreign application 98202707.0 filed in Europe on December 8, 1998. However, the instant application **does not comply** with the rules set out in 35 U.S.C. § 119 (a)-(d) since a certified copy of the original foreign application has not been filed with the Office. Priority to this document is, thus, **DENIED**. Applicants noted in response that a certified copy was sent to the Office on February 28, 2003; however, the copy received was not an official certified copy with ribbons. Copies are not acceptable. Moreover, the introduction of pages 3-4 after-the-fact is also not acceptable. A complete, ribboned, certified copy from the European patent office is required to perfect the claim to foreign priority.

In the instant Office action, the priority date used is that of the parent application, PCT/EP99/05473 filed on July 26, 1999, claimed as a continuation in the transmittal sheet.

Withdrawn – Objections to the Specification

3. Previous objection to the specification for having improper margins (see M.P.E.P. § 608.01) is withdrawn by virtue of Applicant's proper filing of a substitute specification.

Maintained – Objections to the Specification

4. Previous objection to the specification for the following informalities and/or confusions is maintained. Applicant argues that the amendment to the specification on page 5 clearly identifies the genes as being GenBank accession numbers; the Examiner disagrees. The specification, as amended, reads: “the X17390 gene, the X14490 gene, or the X53657 gene (GenBank accession numbers)”. This is an improper iteration of GenBank numbers since the genes are not named by the numbers, the genes themselves have names. The Examiner suggests the following for amendment to the specification, for clarity:

---the genes of GenBank Accession number X17390, GenBank Accession number X14490, or GenBank Accession X53657---

Applicant also argues that “FUM medium” is well known in the art by virtue of its appearance in Gmur *et al.* and Loesche *et al.* While the Examiner can find no mention of “FUM media” in Loesche *et al.*, the media is clearly defined in Gmur *et al.* If this media is intended, the specification should recite this reference. The objection is maintained until the specification is amended to do so.

New - Objections to the Claims

5. Claim 10 is objected to for having a typographical error. In line 1, the word “herein” should be ---wherein---. Correction is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

6. Previous rejection of Claims 1, 3, 6-10, and 23-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “lactic bacteria that are not part of the resident

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microflora or the mouth" is withdrawn by virtue of Applicant's amendment to insert "human mouth" into the claim. Since the bacteria of the human mouth are known in the art, this term is now clear.

Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

7. Previous rejection Claim 6 and new rejection of Claims 25-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" with respect to a temperature or a weight percent is amended. Applicant argues that the term has been deleted for the purpose of the withdrawal of the rejection; for Claim 1 this is the case and the rejection has been dropped. For Claim 6 and the new rejection of Claims 25-26, this is not the case. Applicant had previously argued that the term "about" is "explicitly endorsed by the M.P.E.P.". As previously noted, this is an oversimplification. The M.P.E.P. § notes that the word "about" is not automatically unclear provided that the specification provides some degree of breadth for the term it is meant to broaden. For example, error percents, variety in experimental procedures, etc. would all indicate the breadth of the "about" term so that one of skill in the art could ascertain the metes and bounds of the claimed invention.

In the instant case, no indication of the breadth of temperature available for Claim 6 is found in the specification. The strains in the examples are all grown at either 30°C or 37°C; how is one of skill in the art supposed to judge the scope of "about 37°C"? Is 30°C within the scope of the invention? Similarly for "about ____ % weight of the composition", no examples of adding bacteriocin or milk derivatives to the composition are found in the specification. How is one of skill in the art supposed to judge the scope of "about 3% weight of the composition" when no

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examples, with or without breadth, exist in the specification? Clarification of the breadth of the term “about” in the instant claims is required.

8. Previous rejection of Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “of dairy origin” is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive. Applicants argue that the term “of dairy origin” is well-known in the art as evidenced by its use in a U.S. patent title. The Examiner disagrees. As previously noted, the instant specification is replete with examples of recombinant DNA and strain technologies. Thus, in the field under which the instant application is filed, the term “dairy origin” requires clear definition. Must the lactic bacteria be naturally occurring? If not, how many alterations to a naturally occurring dairy lactic acid bacteria strain can be made before the strain is considered “of different origin”? None of these issues, previously set forth for Applicant’s comment, have been clarified. Clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

9. Previous rejection of Claim 7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant’s amendment to include specific ways to improve adherence in the claim.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

10. Previous rejection of Claims 1, 3, 4, 6, 7, 9, 10, and 23-28 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive. Applicant argues that Dr. Gmur’s declaration convincingly

asserts that the instant claims have adequate written description; the Examiner disagrees. As noted in Applicant's remarks, Dr. Gmur declares that one of skill in the art could either use the five lactic acid bacteria specifically disclosed in the invention or could make more, similar bacteria by the means taught in the specification. While this may be true, this ENABLES the claimed invention; the instant rejection is one of written description.

Applicant also argues that *Amgen*, and not *Lily*, is an appropriate precedent for the pending claims; the Examiner disagrees. In *Amgen* the written description of a characterized protein product from a specific DNA sequence being made in a mammalian cell is at issue as to whether two species of mammalian cell expression of the protein provides adequate written description for the genus of the protein being expressed in any mammalian cell. In the instant case, Applicant would have the five examples of specifically functioning lactic acid bacteria support the claimed genus of all lactic acid bacteria with this claimed function for use in the claimed methods wherein no correlation between structure and function is described. While equivalent protein expression of two mammalian cells can adequately describe the genus of proteins expressed in all mammalian cells, the subset of lactic acid bacteria for use in the claimed invention cannot without some indication of the correlating structure – a point specifically made in *Enzo Biochemical*.

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described (this is in contrast to the five

examples of lactic acid bacteria useable in the claimed methods), the same analysis applies wherein the product, used in the claimed methods, must have adequate written description of (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed as iterated in *Enzo Biochemical*. While several species are disclosed in the instant specification, no identifying characteristics of the claimed lactic acid bacteria (i.e., structure/function) are disclosed so as to describe the breadth in Claim 1. Thus, the instant claims lack adequate written description and do not support the breadth of the instant claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

11. Previous rejection of Claims 1, 3-4, 6, 9, and 28 under 35 U.S.C. § 102(b) as being anticipated by Madinier (WO 92/14475) is withdrawn. With a clear limitation of pH requirements, which limitation is not taught expressly by Madinier *et al.*, the rejection must be withdrawn.

12. Previous rejection of Claims 1, 3-4, 6, and 28 under 35 U.S.C. § 102(b) as being anticipated by Busscher *et al.* is withdrawn by virtue of Applicant's amendment to include a clear limitation of a pH requirement not taught by Busscher *et al.*

Summary of Pending Issues

13. The following is a summary of the issues pending in the instant application:

- a) Official priority documents must be received of the claim to priority cancelled.
- b) The specification stands objected to for informalities and/or confusions relating to GenBank numbers and FUM media.
- c) Claim 10 stands objected to for a typographical error.
- d) Claims 6 and 25-26 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" due to its unclear metes and bounds.
- e) Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "of dairy origin".
- f) Claims 1, 3, 4, 6, 7, 9, 10, and 23-28 stand rejected under 35 U.S.C. 112, first paragraph, written description.

Conclusion

14. Claim 29 is allowed in the Office action; claims 1, 3, 4, 6, 7, 9, 10, and 23-28 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

April 30, 2004